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Biotechnology

Registration Procedure for GMO Feeds

2007

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Report Highlights:
This report provides an unofficial translation of the procedure to register feeds produced from genetically modified organisms (GMOs). In accordance with the resolution of the Russian Government that transferred the testing and registration of biotechnology feeds from the Ministry Of Agriculture to the Federal Service for Veterinary and Phytosanitary Surveillance (VPSS), VPSS developed the administrative statute (procedure) for registration. The draft was posted on the Ministry of Agriculture's website for comments and discussion at the end of August 2007. Sources report that VPSS has already accepted applications based on the procedures described in the draft.

Includes PSD Changes: No
Includes Trade Matrix: No
Trade Report
Moscow [RS1]
[RS]

In July 2006, the Federal Service for Veterinary and Phytosanitary Surveillance (VPSS) assumed the responsibilities for testing and registration of biotechnology feeds from the Russian Ministry of Agriculture[1]. Following the transfer, the Ministry of Agriculture and VPSS developed an internal document on the procedures for registering biotechnology feeds, and offered the draft for public discussions and comments. The process to develop a draft that complies with Russian legislative standards took almost a year, although experts report that the draft procedure is similar to what the Ministry of Agriculture had before the transfer of duties. This draft was posted on the Russian Ministry of Agriculture website at the end of August for comments and discussion[2]. Sources believe the draft will be signed by the Minister of Agriculture without any changes or additions. Moreover, VPSS has already started to accept registration applications for biotechnology events and feeds, and the actual procedure is exactly the same as described in the draft. Every individual contract that the applicant concludes with VPSS contains the description of this procedure.

The unofficial translation of the draft procedure of registration of biotechnology feeds follows.

Draft
Approved by the Order
of the Ministry of Agriculture

of the Russian Federation
«_»_____200_ ? _____

ADMINISTRATIVE STATUTE

OF THE FEDERAL SERVICE FOR VETERINARY AND PHYTOSANITARY SURVEILLANCE TO FULFILL THE STATE FUNCTION TO REGISTER THE FEEDS MANUFACTURED FROM GENETICALLY ENGINEERED MODIFIED ORGANISMS

1. General provisions

1.1. The Administrative Statute covering the fulfillment of the state registration of feeds (hereinafter referred to as the Statute)[3] manufactured from genetically modified organisms (hereinafter referred to as the GMO), created by the Federal Service for Veterinary and Phytosanitary Surveillance[4], determines Rosslkhoznadzor's timeframes and administrative procedures for federal registration of feed manufactured from GMOs and issuing certificates for federal registration.

Registration of GMO feeds will comply with the following legislative acts:

A. Federal Law No. 86-F3 "On The State Regulating In The Area Of Genetic Engineering Activity" July 5th, 1996[5].

[1] For more information see GAIN RS6039 New Resolution Transfers GMO Feed Registration Duties to VPSS

[2] http://www.mcx.ru/index.html?he_id=900&doc_id=15400

[3] Feeds include the products of plants, animals and micro-biological origin as well as their components that are used to feed the animals, which contain the nutrients that can be assimilated and that do not have a negative effect on the animals' health.

[4] Hereinafter referred to as Rosselkhoznadzor. English abbreviation of Federal Service for Veterinary and Phytosanitary Surveillance is VPSS.

[5] Amended on July 12, 2000.

B. Federal Law No. 184-F? "On technical regulation" of December 27, 2002
C. Statutory Document "On the Federal Service For Veterinary and Phytosanitary Surveillance" approved by Resolution No. 327 of the Russian Government on June 30, 2004.
D. Russian Government Resolution No. 26 approved January 18, 2002, "On the state Registration of the Feeds Manufactured from Genetically Engineered Modified Organisms".[6]
E. Statutory Document "On the State Registration of the Genetically Engineered Modified Organisms", approved by Russian Government Resolution No. 120 on February 16, 2001.

1.2. Rosselkhoznadzor will establish an Expert Board (advisory committee) to evaluate materials submitted for federal registration of feeds and input materials (raw materials) manufactured from GMOs (hereinafter referred to as the Expert Board). The Expert Board will ensure objectivity and consistent quality when reviewing safety data about GMO feeds submitted by applicants. The composition of the Expert Board must be approved by the Head of the Rosselkhoznadzor.

1.3. Certificates for GMO feeds will be issued for five-year terms with an option to recertify for an additional five years.

1.4. The Russian Ministry of Agriculture will maintain the state registry of approved GMO feeds[7].

1.5. Russian Federation law authorizes Rosselkhoznadzor to reverse (annul) the certification of registered GMO feeds followed by the appropriate entry in the state registry[8].

1.6. The address to submit documentation and applications is as follows:

Orlikov per., 1/11, Moscow, 107139, Rosselkhoznadzor[9].
The telephones for preliminary appointments and inquiries are as follows:
(495) 207-07-41;

Zvenigorodskoye Schosse, 5, Moscow, 123022, FGU (VGNKI)[10].
The telephone number for preliminary appointments and inquiries is as follows:
(495) 253-14-73.

1.8. Applicants are prohibited from registering different types of GMO feeds or input materials (raw materials) under the same name (title).

1.9. Applicants are prohibited from registering the same GMO feed multiple times under the same name (title) or different names (titles).

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[6] Amended by the Resolution of the Government of the Russian Federation of July 14, 2006, ? 422).
[7] Data on the registered GMO feeds is available on the official site of the Russian Ministry of Agriculture http://www.mcx.ru, and is updated as needed.
[8] Information about Rosselkhoznadzor is posted on the official portal of the Russian Federation Ministry of Agriculture http://www.mcx.ru
[9] Address in Russian is: ??????? ???., ?. 1/11, ??????, 107139, ??????????????
[10] Address in Russian is: ?????????????? ????? ?. 5, ??????, 123022, ??? «?????»

2. Administrative Procedures

2.1. Rosselkhoznadzor, or its subsidiary federal state establishment, the All-Russian Center for Quality and Standardization of Veterinary Pharmaceuticals and Feeds[11] (hereinafter referred to as – FGU «VGNKI») carries out the federal registration of GMO feeds by:

?) Accepting, recording, and considering registration applications for GMO feeds and the materials attached to the application;

b) Issuing registration certificates for GMO feeds, and authorizing its delivery into the territory of the Russian Federation.

2.2. The certification process for previously unregistered GMO feed(s) may require two additional years due to additional testing required for biological safety.

2.3. The administrative procedures, including the procedures to obtain GMO certification, and the timeframes to conduct the certification, are listed in Attachment 1.

2.4. Acceptance and consideration of the application and materials to federally register GMO feeds or the input materials (raw materials) manufactured from the GMO is carried out as follows:

The legal entity or the physical entity that produces or imports the feeds (hereinafter referred to as – the Applicant) will submit the following to the FGU (VGNKI):

a) An application for federal registration of the GMO feed(the application form is listed in Attachment 2);
b) Materials containing the following:
   i. Data regarding the origin of the GMO feed
   ii. Evaluation of the potential dangers resulting from the use of GMO feeds (compared to the original basic feed or input material) and applicant's recommendations to decrease the danger;
   iii. Data on the end use of GMO feed and data on the registration and the use of the feed in question abroad;
   iv. Data on the technology used to grow the variety of the modified plant used to manufacture the feed;
   v. Data on the technology used to manufacture the GMO feed, including a draft instruction for use of the GMO feed.
c) In circumstances where the plant variety used to manufacture feed is able to reproduce itself, and is intended for subsequent growth of bio-mass and fodder grain, the applicant will submit a copy of the registration certificate of the modified plant to the Federal Register of Selection Achievements Allowed for Cultivation;
d) The power of attorney from the company producing the feed;
e) In circumstances where the applicant commissioned an evaluation or assessment of the GMO feed from relevant experts, the results of the evaluation may be submitted as part of the application package for GMO registration.

2.5. All documents to register GMO feed will be submitted in the Russian language, or must have a certified Russian translation. The applicant is responsible for the authenticity of the data listed in the application and the materials attached to the application.

2.6. The FGU (VGNKI's) division responsible for registering GMO feeds will verify completeness and authenticity of the submitted data within three days of receipt to determine the following:

[11] The Russian name for the center is «????????????? ?????????????? ????? ???????? ? ?????????????? ????????????? ??????? ??? ???????? ? ??????» (??? ?????)

a) The applicant submitted all mandatory documents as per paragraph 2.4;
b) The consistency of the information submitted in the application;
c) Document authenticity; confirmed by the signature of the head of the organization on every document.

2.7. Within three days of receipt, the FGU (VGNKI) will forward the registration application and the draft of the instruction to use the GMO feed to Rosselkhoznadzor,. The application can be rejected in the following cases:

a) The set of the documents is not complete;
b) The documents submitted are not consistent;
c) The registration application and/or the draft of the instruction to use the GMO feed have not been developed in accordance with the forms (Attachments 1 and 2 to this Statute);

d) The documents' copies have not been certified adequately resulting in the impossibility to confirm the authenticity of the documents submitted;
e) The certified translation of the documents submitted into the Russian language is not available;
f) The power of attorney from the company producing the feed is not available or is not valid.

2.8. If the GMO feed application is accepted, then the application will be registered in the Rosselkhoznadzor with a file number assigned to the application. The department head will appoint a "responsible performer" (hereafter referred to as responsible performer) charged with reviewing the application and the draft of the instruction to use the GMO feed. The applicant has the right to request the surname, name, patronymic and the office telephone of the responsible performer. The applicant may request this information verbally or in writing.

2.9. The responsible performer will develop a registration packet containing the application and the draft instruction on feed usage, in addition to other relevant documents or materials. The draft instruction is replaced by the approved instruction, upon registration of the GMO feed, and the case is archived with Rosselkhoznadzor.

2.9.1. If the application is rejected, then the registration process is suspended, and Rosselkhoznadzor will notify the applicant in writing and request missing documents, or recommend amendments to the applicant's existing documents. The registration is denied if the applicant fails to respond within 30 days of receiving the notification.

3. Expert Board Procedures

3.1. Within 14 days of receipt of the completed application, the responsible performer will compile a list of feed applications and submit the list to the Expert Board.
The Expert Board will meet as required to review GMO feed applications, but not less than once every quarter.

3.2. Within 30 days the Expert Board will review the safety data submitted by the applicant and the manufacturing methods used in creating the GMOs. If the data is not sufficient, the Expert Board will request additional safety information or recommend to the applicant additional testing at an accredited testing facility.

3.3. If the applicant fails to present additional safety information within three months of notification from the Expert Board, the FGU (VGNKI) will notify the applicant in writing that

the Expert Board is unable to conclusively judge the safety of the GMO feed. A copy of this notification is added the applicants file at the Rosselkhoznadzor.

3.4. Recommendations to approve or suspend the application are based upon the application packet, including the testing protocols, submitted by the applicant. The Expert Board may not recommend approval if there is scientifically substantiated data that the GMO feed threatens the lives or health of animals.

3.5. Recommendations to approve the registration are forwarded to Rosselkhoznadzor within ten days of the Expert Board's decision. The recommendations are communicated through an official letter signed by the Chairman of the Expert Board. A list of GMO feeds recommended for registration (with instructions on their use) will accompany the official letter, in addition to and notifications of registration suspensions, with reasons for the suspensions.

4. Registration and Issuance of the Registration Certificate

4.1. Rosselkhoznadzor will decide to approve or reject the applicant's registration within 20 days of receiving the Expert Board's recommendations. If registration is approved, Rosselkhoznadzor assigns a file number to the registration and forwards the information to the FGU (VGNKI). FGU will assign a registration number to the GMO feed and issue the registration certificates within ten days of receiving the approval from Rosselkhoznadzor. The registration certificate will be forwarded to Rosselkhoznadzor for final signatures from the head of Rosselkhoznadzor, or an official acting on his/her behalf. After the signatures, the responsible performer will inform the applicant that the federal registration passed and is available at Rosselkhoznadzor

4.2. The responsible performer will forward the information about the federal registration to the Ministry of Agriculture of the Russian Federation for entry into the State Registry of GMO Feed (hereinafter referred to as – the Registry).

4.3. If Rosselkhoznadzor rejects the registration, then the applicant is notified in writing within five days of Rosselkhoznadzor's decision with details specifying reasons the registration was not approved.

5. Extending the Validity of the Federal Registration Certificate

5.1. Within three months of the expiration date of the original certificate, the owner must submit an application to Rosselkhoznadzor requesting an extension of the registration to prevent the certificate from expiring. The re-registration procedure is similar to the original registration

6. Annulment of the Federal Registration Certificate

6.1. Certificates can be annulled if either or both of the following conditions are satisfied:

a) First, if animal health officials discover a relationship between GMO feed usage and deterioration in animal health.
b) Second, the adulteration of the GMO feed by modified organisms not registered in the Russian Federation.

If these conditions are satisfied, then the GMO feed is required to be withdrawn from handling followed by the appropriate entry in the Registry. Rosselkhoznadzor will notify the relevant federal executive authorities within 15 days of the date the decision was made to annul the certificate.

6.2. Refusal to administer federal registration procedures for certifying GMO feed, as well as annulments of the certificate of GMO feed registration, may be appealed in court.

7. The Appeals Process

7.1. If a Russian Federation citizen disagrees with a decision reached by Rosselkhoznadzor, or its territorial bodies, then they have the right to appeal to the higher level official (or organization) and/or to the courts. The appeal must be filed within the time allowed by law, and follow pre-court and court procedures. The Ministry of Agriculture of the Russian Federation controls the activities of Rosselkhoznadzo. Rosselkhoznadzor controls the activities of its territorial bodies.

7.2. Appeals may be filed based on the following circumstances:

a) Appeals based on decisions reached by the territorial bodies of the Rosselkhoznadzor may be filed with the Rosselkhoznadzor;
b) Appeals based on decisions reached by the Rosselkhoznadzor may be filed with the head of the Rosselkhoznadzor;
c) Appeals based on decisions reached by the head of the Rosselkhoznadzor may be filed with the Ministry of Agriculture of the Russian Federation. Including if the head of Rosselkhoznadzor does not take actions guaranteed by Russian law relating to the action (or inaction) of Rosselkhoznadzor's officials or its territorial bodies.

7.3. Applicants have the right to submit appeals verbally, or send written appeals to local or regional government bodies, and federal officials.

7.4. Applicants will exercise their right to appeal freely and voluntarily, and appeals are carried out free of charge. The freedoms of other persons will not be violated by the citizens exercising their right to appeal.

7.5. The head of Rosselkhoznadzor and heads of its territorial bodies will set up appointments with individual citizens. The time and location of these appointments will be published for the public.

7.6. Applicants will present the documents identifying themselves when coming to an individual appointment. Citizens may submit oral or written testimony during the appeals process. Oral testimony will become part of the appointment record. Written testimony must be registered and follow the procedures established for written appeals. After reviewing the appeal, if a conclusion is reached that does not require additional investigation, then the applicant will receive a verbal reply (with their consent) during the individual appointment. In such a case, an appropriate note is made in the individual person's appointment card. In the remaining cases the reply is given in writing.

7.7. If the appeal contains questions requiring a decision not within the competence of Rosselkhoznadzor, its territorial body or the official, then the applicant will receive instructions on the appropriate procedures to follow.

7.8. The applicant may be refused an appeal, during the individual appointment, if he/she previously received a reply relating to the issues in their appeal. The applicants have the right to send a written proposal, statement, or complaint (hereinafter referred to as – written statement) in response to the refusal of an appeal. The term to consider the written statement will not exceed 30 days from the moment it is registered.

7.9. In exceptional circumstances the head of Rosselkhoznadzor, or the head of a territorial body, has the right to extend the term to consider the appeal for not more than 30 calendar days. The applicant must be notified about extending the term to consider his/her appeal. These circumstances may include:

a) A decision to verify information submitted during testimony, or request additional documentation and materials from the appropriate territorial body.
b) Requesting information from other governmental bodies, the bodies of local government, or to other officials requesting necessary documents and materials to consider the appeal.

7.10. Russian Federation legislation details procedures to extend the term to consider appeals. In his/her written statement, the applicant is required to indicate the governing body where the written statement was sent, or the surname, name, patronymic of the appropriate official, or the position of the appropriate official. The applicant must also indicate his/her surname, name, patronymic (the latter – if available), the full title (name) of the legal entity, and the mailing address where the reply is to be sent. If the applicant's return addresses changes, then the applicant must notify the officials of the new return address. The applicant must spell out the nature of the proposal, the statement, or the complaint, and include the date and their signature.

7.11. Additionally the written statement may contain the following:

a) The title, surname, name and patronymic name of the specialist whose action (inaction) constitutes the subject of the appeal (if such information is available);
b) The nature (circumstances) of the action (inaction) that constitutes the subject of the appeal; grounds which the applicant considers to be the reasons why his/her rights, freedoms, and legal interests have been violated and that obstacles erected to implement the above-mentioned, or a certain burden has been illegally placed on him/her; as well as other data that the applicant considers relevant.
c) If it is necessary to confirm the reasoning behind the appeal, then the applicant may attach documents and materials or their copies to the written statement.

7.12. Rosselkhoznadzor's official (or the territorial body of the Rosselkhoznadzor's) will make a decision to approve or refuse the applicant's claims after deliberating the applicant's case.

7.13. A written response containing the decision will be delivered to the applicant. If the written statement does not contain the surname and mailing address of the applicant, then the appeals court decision will not be delivered.

8. Reasons an Applicant's Appeal May Not Be Considered

8.1. During the appeals process the applicant may not receive a response under the following circumstances:

a) Upon receiving a written statement that contains extremely rude or obscene expressions, threats to life, health or property of the official as well as of the members of his/her family, Rosselkhoznadzor or the territorial bodies have the right to disregard the statement without responding to the nature of the issues, and inform the applicant who sent the address about the impermissibility of abusing the legislation.
b) If the text of the written statement is not legible, then the response to the statement is not given and the applicant is informed about it; provided his surname and address are legible.

c) If the written statement of the applicant contains a question that was the subject for numerous previous written replies sent to the applicant on similar issues, and the present address does not contain new proofs or circumstances, then the Head of the Rosselkhoznadzor, or the territorial body, has the right to terminate correspondence with the applicant. Correspondence can be terminated if the statement in question and the previous statements were sent to the Rosselkhoznadzor, one of the territorial bodies of Rosselkhoznadzor, or to one and the same official. The applicant that sent the address will be informed about such a decision.
d) If the response relating to the nature of the issue cannot be developed without disclosing the data that constitute a state secret, or other secrets that are protected by federal legislation, then the applicant will be informed that federal secrecy legislation prohibits a reply to his/her appeal.

8.2. If the reasons preventing the development of a response are removed, however, then the applicant has the right to send the revised statement to Rosselkhoznadzor or to its territorial body.

9. Procedure to File Complaints

9.1. The statement containing complaints against Rosselkhoznadzor's decision will be returned to the applicant with explanations on the procedure to appeal against the particular judgment.

9.2. The applicants have the right to complain about the decisions taken in the course of implementing the state function, action, or inaction by officials from the Rosselkhoznadzor in court.

9.3. The applicants can post their opinions about violations of their rights and legal interests, illegal decisions, action or inaction on the part of the officials from Rosselkhoznadzor, violations of the stipulations of the Administrative Statute, non-correct behavior or violations of the official ethics on the Internet-site, or using electronic mail of the bodies that exercise the state function.

9.4. Applicants filing a complaint should include the following information:
a) The surname, name and patronymic of the citizen (name of the legal entity) submitting the complaint, a registered permanent or temporary residence;
b) The name of the body, position, surname, name and patronymic of the official (if such information is available), whose decision, action (inaction) violates the rights and legal interests of the applicant;
c) The nature of violation of the rights and legal interests of the applicant, of the illegal decision, action (inaction);
d) The applicant's contact information to inform the applicant about the measures taken based on the results of his/her application's consideration.

Attachment 1
to the Administrative Statute

Consideration of the documents and developing decisions about the federal registration of the feed manufactured from the GMO

?	Administrative procedure	Term	Performer	Notes
1	The applicant submits the application and materials		Applicant	
2	The data and materials submitted by the applicant are accepted and checked	7 days	the FGU «VGNKI», the Rosselkhoznadzor	
3	Materials and testing protocols are reviewed by the Expert board	30 days	Expert board	
4	The registration certificate is registered and issued	30 days	the Rosselkhoznadzor	
5	Extending the term of validity of the certificate about the federal registration of the feed, manufactured from the GMO		This is analogous to the procedure of the federal registration	

Attachment ? 2 to the Administrative Statute

APPLICATION

I request registration in the Russian Federation of the feed manufactured from genetically-engineered-modified organisms,

_____

1. Applicant

_____

2. Applicant's address, telephones, fax, telex, INN and other data _____

?	Administrative procedure	Term	Performer	Notes
1	The applicant submits the application and materials		Applicant	
2	The data and materials submitted by the applicant are accepted and checked	7 days	the FGU «VGNKI», the Rosselkhoznadzor	
3	Materials and testing protocols are reviewed by the Expert board	30 days	Expert board	
4	The registration certificate is registered and issued	30 days	the Rosselkhoznadzor	
5	Extending the term of validity of the certificate about the federal registration of the feed, manufactured from the GMO		This is analogous to the procedure of the federal registration	

3. Applicant's representative

_____

(surname, name, patronymic, address, telephone, fax, ? of the power of attorney)

4. Data on the feed:

Generally recognized name_____

Trade name_____

4.3.1Data on the genetically-engineered-modified organism_____

Form_____

Feed's purpose/function _____

Availability of the patent, its number, its owner _____

Availability of the certificate for the trade name/title of the feed, number of the certificate

___

Feed developer_____

(address, telephone, fax)

Feed manufacturer_____

(address, telephone, fax)

The application is filed:

« »_____

Applicant's signature (applicant's representative signature)

Stamp (surname, name, patronymic, position occupied)

Attachment ? 3

To the Administrative regulation

APPROVED
Deputy Head
of the Rosselkhoznadzor

E.A. Nepoklonov

«___» _____ 200 __

INSTRUCTION
To use (name/title of the feed)
for (area of the feed's use, for whom),
containing genetically-engineered-modified organisms

Manufacturer: company, country (in the Russian language)
company, country (in the English language)

1.GENERAL DATA

1.1 Feed title/name.
1.2 Enumeration of all the components in the feed composition specifying genetically-engineered-modified organisms.
1.3 Enumeration of the nutritious substances of the feed specifying their qualitative composition in a feed's unit (please specify the range from … to).
1.4 Stability, possibility and terms and conditions of temperature processing.
1.5 Form of delivery. Packaging, wrapping, storage terms and conditions, transportation terms and conditions and use-by-date.

2. APPLICATION PROCEDURE

2.1. Procedures and terms and conditions to use the feed indicating the type, gender and age of the animal group, dosages, etc.

2.2. Possible side effects and complications, including the ones relating to the genes' modification. Prevention measures and measures to decrease the danger.

2.3. Contraindications for use.

3. PERSONAL PREVENTION MEASURES